

notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the nonabsorbable expandable hemostatic sponge for temporary internal use they intend to market.

## II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

## IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. K130218: De novo request per 513(f)(2) of the Federal Food, Drug, and Cosmetic Act from RevMedx, Inc., dated January 28, 2013.

## List of Subjects in 21 CFR Part 878

Medical devices, General and plastic surgery devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

## PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 878.4452 to subpart E to read as follows:

### § 878.4452 Nonabsorbable expandable hemostatic sponge for temporary internal use.

(a) *Identification.* A nonabsorbable expandable hemostatic sponge for temporary internal use is a prescription device intended to be placed temporarily into junctional, non-compressible wounds, which are not amenable to tourniquet use, to control bleeding until surgical care is acquired. The sponges expand upon contact with blood to fill the wound cavity and provide a physical barrier and pressure that facilitates formation of a clot. The device consists of sterile, nonabsorbable radiopaque compressed sponges and may include an applicator to facilitate delivery into a wound.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Performance data must demonstrate the biocompatibility of patient-contacting components.  
(2) Performance data must demonstrate the sterility of patient-contacting components including endotoxin and pyrogenicity assessments.

(3) Performance data must support device stability by demonstrating continued sterility of the patient-contacting components of the device, package integrity, and device functionality over the requested shelf life.

(4) Assessment of material characteristics must be sufficient to support safety under anticipated conditions of use. Assessments must include the following:

(i) Material specifications.  
(ii) Immunogenicity.  
(iii) Viral inactivation for animal-derived materials.

(5) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Absorption capacity.  
(ii) Extent of swelling.  
(iii) Mechanical properties.  
(iv) Expansion force/pressure.  
(v) Radiopacity.  
(vi) Deployment/applicator functionality.

(6) In vivo performance data must demonstrate safe and effective use by verifying that the device performs as intended under anticipated conditions of use. Appropriate analysis/testing must demonstrate that the product: Controls bleeding, does not promote

adverse local or systemic effects, and can be completely removed from the wound. The following performance characteristics must be tested:

(i) Deployment.  
(ii) Control of bleeding.  
(iii) Radiopacity.  
(iv) Retrieval.  
(v) Assessment of local and systemic effects.

(7) Human factors testing and analysis must validate that the device design and labeling are sufficient for appropriate use by emergency responders deploying the device as well as surgeons retrieving the device from wounds.

(8) Labeling must include:  
(i) Specific instructions for deployment by emergency responders and retrieval by surgeons.

(ii) Warnings, cautions, and limitations needed for safe use of the device.

(iii) Information on how the device operates and the typical course of treatment.

(iv) A detailed summary of the in vivo and human factors testing pertinent to use of the device.

(v) Appropriate imaging information to ensure complete retrieval of device.

(vi) An expiration date/shelf life.

Dated: June 10, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–13905 Filed 6–13–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### 24 CFR Parts 1710, 1715, 1720, 3400, and 3500

[Docket No. FR–5788–F–01]

RIN 2501–AD67

### Removal of Regulations Transferred to the Consumer Financial Protection Bureau

**AGENCY:** Office of the Secretary, HUD.

**ACTION:** Final rule.

**SUMMARY:** Through this rule, HUD removes its regulations previously authorized under the Real Estate Settlement Procedures Act of 1974 (RESPA), the Secure and Fair Enforcement for Mortgage Licensing Act of 2008 (SAFE Act), and the Interstate Land Sales Full Disclosure Act (ILSFDA). Responsibility for administration of these statutes, including authority to issue regulations, was transferred to the Consumer Financial Protection Bureau (CFPB)

pursuant to title X of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). Accordingly, HUD's regulations for these statutes are no longer operative, and are being removed by this final rule.

**DATES:** *Effective Date:* July 16, 2014.

**FOR FURTHER INFORMATION CONTACT:**

Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410; telephone number 202-708-1793 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service at 800-877-8389 (this is a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Dodd-Frank Act<sup>1</sup> transferred from HUD to the CFPB the authority to administer, enforce, and otherwise implement the RESPA (12 U.S.C. 2601 *et seq.*), the SAFE Act (12 U.S.C. 5101 *et seq.*), and the ILSFDA (15 U.S.C. 1701 *et seq.*).<sup>2</sup> Until enactment of the Dodd-Frank Act, the responsibility to administer, enforce, and otherwise implement these statutes was placed on HUD. Under HUD's authority, HUD's issued regulations implementing these laws were codified at 24 CFR part 3500 for RESPA, 24 CFR part 3400 for the SAFE Act, and 24 CFR parts 1710, 1715, and 1720 for the ILSFDA. The transfer of authority to the CFPB occurred on July 21, 2011,<sup>3</sup> and the CFPB has since issued its own regulations for these statutes.<sup>4</sup> Entities covered by these statutes must now comply with the regulations issued by the CFPB. Accordingly, HUD is removing the regulations from title 24 of the Code of Federal Regulations.

**II. Justification for Final Rulemaking**

Pursuant to the Administrative Procedure Act (APA), notice and comment are not required prior to the issuance of a final rule if an agency, for good cause, finds that "notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."<sup>5</sup> HUD finds that public notice and comment are not

necessary for this rulemaking because the Dodd-Frank Act transferred all authority, including rulemaking authority, for RESPA, the SAFE Act, and the ILSFDA to the CFPB as of July 21, 2011. Therefore, HUD's rules for these laws are no longer operative. The removal of these regulations from title 24 of the Code of Federal Regulations is clerical in nature and will reduce any possible confusion that may result from having two sets of rules addressing these laws.

For these reasons, HUD has determined that it is unnecessary to delay the effectiveness of this rule in order to solicit prior public comment.

**III. Findings and Certification**

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Because HUD has determined that good cause exists to issue this rule without prior public comment, this rule is not subject to the requirement to publish an initial or final regulatory flexibility analysis under the RFA as part of such action.

*Unfunded Mandates Reform*

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)<sup>6</sup> requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. If a budgetary impact statement is required, section 205 of UMRA also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule.<sup>7</sup> However, the UMRA applies only to rules for which an agency publishes a general notice of proposed rulemaking pursuant to the APA.<sup>8</sup> As discussed above, HUD has determined, for good cause, that the APA does not require general notice and public comment on this rule and, therefore, the UMRA does not apply to this final rule.

*Executive Order 13132, Federalism*

Executive Order 13132 (entitled "Federalism") prohibits an agency from

publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This final rule will not have federalism implications and would not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

*Environmental Review*

This final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern, or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this final rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

**List of Subjects**

*24 CFR Part 1710*

Consumer protection, Land sales, Reporting and recordkeeping requirements.

*24 CFR Part 1715*

Advertising, Consumer protection, Fraud, Land sales.

*24 CFR Part 1720*

Administrative practice and procedure.

*24 CFR Part 3400*

Licensing, Mortgages, Registration, Reporting and recordkeeping requirements.

*24 CFR Part 3500*

Consumer protection, Housing, Mortgages, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, and under the authority of 42 U.S.C. 3535(d), title 24 of the Code of Federal Regulations is amended as follows:

**PART 1710—[REMOVED]**

■ 1. Remove part 1710.

**PART 1715—[REMOVED]**

■ 2. Remove part 1715.

<sup>1</sup> Public Law 111-203, 124 Stat. 1376, approved July 21, 2010.

<sup>2</sup> 12 U.S.C. 5581. See Dodd-Frank Act, section 1061(b)(7).

<sup>3</sup> See <http://www.gpo.gov/fdsys/pkg/FR-2010-09-20/pdf/2010-23487.pdf>.

<sup>4</sup> See 12 CFR part 1024 for RESPA, 12 CFR parts 1007 and 1008 for the SAFE Act, and 12 CFR part 1024 for ILSFDA.

<sup>5</sup> 5 U.S.C. 553(b).

<sup>6</sup> 2 U.S.C. 1532.

<sup>7</sup> 2 U.S.C. 1534.

<sup>8</sup> 2 U.S.C. 1532(a).

**PART 1720—[REMOVED]**

- 3. Remove part 1720.

**PART 3400—[REMOVED]**

- 4. Remove part 3400.

**PART 3500—[REMOVED]**

- 5. Remove part 3500.

Dated: June 10, 2014.

Shaun Donovan,  
Secretary.

[FR Doc. 2014–14007 Filed 6–13–14; 8:45 am]

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**DEPARTMENT OF HOMELAND  
SECURITY**
**Coast Guard****33 CFR Part 117**

[Docket No. USCG–2013–1072]

RIN 1625–AA09

**Drawbridge Operation Regulation;  
Terrebonne Bayou, LA**

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

**SUMMARY:** The Coast Guard is finalizing the interim rule that governs the operating schedule of the St. Ann swing bridge across Terrebonne Bayou, mile 28.8, at Bourg, Terrebonne Parish, Louisiana. The rule will allow the bridges to operate on signal if at least 24 hours advanced notice is given. This rule increases the efficiency of operations allowing for the safe navigation of vessels through the bridge while recognizing the low volume of vessel traffic through the bridge.

**DATES:** This final rule is effective June 16, 2014.

**ADDRESSES:** Documents mentioned in this preamble are part of Docket Number USCG–2013–1072. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Mr. David Frank; Bridge

Administration Branch, Eighth Coast Guard District; telephone 504–671–2128, email [david.m.frank@uscg.mil](mailto:david.m.frank@uscg.mil). If you have questions on viewing or submitting material to the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

**SUPPLEMENTARY INFORMATION:****Table of Acronyms**

CFR Code of Federal Regulations  
DHS Department of Homeland Security  
USCG United States Coast Guard  
NEPA National Environmental Policy Act  
§ Section Symbol  
U.S.C. United States Code  
MGL Mean Gulf Level  
SR State Route

**A. Regulatory History and Information**

On February 12, 2014, we published an interim rule with request for comments entitled, “Drawbridge Operation Regulation; Terrebonne Bayou, LA” in the **Federal Register** (79 FR 8270). We received no comments on the interim rule. No public meeting was requested, and none was held.

**B. Basis and Purpose**

The U.S. Coast Guard received a request to modify the existing operating schedule of the new St. Ann swing bridge across Terrebonne Bayou, mile 28.8, at Bourg, Terrebonne Parish, Louisiana. The request follows completion of the new swing bridge and accommodates current traffic needs, rather than opening on signal at all times. As requested, the bridge will open on signal if at least 24 hours advanced notification is given.

This change allows the bridge owner to open the bridge for vessel traffic with sufficient notice while removing the requirement that a bridge tender be on the bridge at all times.

Since completion of the new bridge, no openings have been requested by mariners and several of the bridges downstream of the swing bridge are operated under special operating regulations published in 33 CFR 117.505. These special operating regulations increase efficiency and currently operate without issue. The SR 24 (Presquille Isle) bridge, located 2.5 miles upstream of the St. Ann swing bridge at mile 31.3 in Bourg, is a fixed bridge with a vertical clearance of 3.4 feet above mean high water, elevation 3.4 feet Mean Gulf Level (MGL). The primary affect of this change is limited to the property owners located on and vessels transiting this waterway between the St. Ann swing bridge and the SR 24 (Presquille Isle) bridge.

**C. Discussion of Comments, Changes and the Final Rule**

An interim rule with a request for comments was established on February 12, 2014. No comments were received and no objections to the interim rule was received.

No changes to the regulatory text were made between the interim rule and the final rule. Therefore, this final rule retains paragraph (b) of the interim rule in 33 CFR 117.505 for this waterway. Further, it retains paragraph (a) and the redesignation of the already existing paragraphs for bridges at mile markers above 28.8. This rule allows the bridge to open on signal if at least 24 hours advanced notification is given.

As no vessels have transited through this bridge site in the last two years and only 15 openings were requested since 2008, this regulation will have a minimal affect on the property owners located in and vessels transiting the area. Additionally, the bridge can be opened in less than four hours if there is an emergency on the waterway.

**E. Regulatory Analyses**

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes or executive orders.

**1. Regulatory Planning and Review**

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

This rule allows the limited number of vessels using this stretch of the waterway the opportunity to transit with proper notification. As this bridge has not opened for vessel traffic during the two years (11/2011 to 11/2013) that the new bridge was under construction and only 15 times since 2008, this regulation will have a minimal affect on those property owners and vessels who wish to use the waterway.

**2. Impact on Small Entities**

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations